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ROBINS & PASTERNAK
1731 EMBARCADERO ROAD
SUITE 230
PALO ALTO, CA 94303

EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/844,662	RASCHKE ET AL.	
	Examiner	Art Unit	
	ROBERT M. KELLY	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57,68-71,91,93 and 96-102* is/are pending in the application.

4a) Of the above claim(s) *91,93 and 96-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57 and 68-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and argument of 2/26/08 are entered.

Claims 57, 68-71, 91, 93, and 96 have been amended with the present response.

Claims 63, 64, 66, 67, 87-90, 92, 94, and 95 are cancelled.

Claims 57, 68-71, 91, 93, and 96-102 are presently pending.

Note: specification citations

The Examiner will refer to Applicant's specification in terms of the paragraph number of the Application Publication of this Application: Publication No. 2002/0064802, rather than page and line number of the present specification, whenever possible (i.e., the amendments that do not matter to the argument/rejection/objections proffered).

Election/Restrictions

Claims 91, 93, and 96-102 remain withdrawn as being drawn to non-elected inventions, per the restriction requirement of 4/7/04, response to restriction requirement of 5/10/04, and Official Action of 11/14/06, as well as the prosecution history.

Hence, Claims 57 and 68-71 are presently considered.

Claim Status, Cancelled Claims

In light of the cancellation of Claims 63, 64, 66, 67, 87-90, 92, 94, and 95, all rejections and/or objections to such claims rendered moot, and thus, are withdrawn.

Claim Interpretation

It is noted that Applicant's newly amended claim, Claim 57, now is more clear as to its scope. The scope of the examined claims (Claims 57, and 68-71), is provided below for clarity, now that the old scope of the claims has been adjusted to be more clear.

Claim 57 is determined to encompass a cell, which may be *in vivo* or *ex vivo* (i.e., *in vitro*), which cell comprises a complex between a non-naturally occurring Zinc finger protein (i.e., a Zinc finger protein which has been altered in any way from the structure which it is understood to typically comprise in its naturally-expressed form), which Zinc finger protein is bound to a target site in cellular chromatin. It should be noted that the "accessible region" in the claim is non-limiting, as if the Zinc finger protein is bound, it is bound to a region it can access and bind. Further, the term "region" is so broad, there being no definition in the specification to determine what spacing is required, that the region encompasses any position within the cell's DNA which comprises chromatin structure.

Claim 68 requires that the Zinc finger protein is encoded on a nucleic acid introduced into the cell, whether or not the Zinc finger is expressed from the nucleic acid.

Claims 69-71 requires that the cell type be a plant cell, an animal cell, or a human cell, respectively.

Claim Objections

In light of the amendments to Claim 57, the objections to Claims 57 and 68-71, as depending therefrom, are withdrawn.

To wit, the binding site no longer comprises a target site, and the probe-sensitive region is no longer claimed. Hence, the objections are withdrawn for the claims as the limitations are removed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 57 and 68-90 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 7,235,354, for reasons of record, as modified below due to the amendments. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method of regulating gene expression and associations with phenotypes, but does do so in all of the same species of the instant claims, and necessarily requires these non-naturally occurring ZFPs to bind to genomic sequences to express the genes and have the phenotype. The

specification is drawn, at its core to the ZFPs, which includes similar synthetic ZFPs. Hence, in the process of performing the method, the ZFPs would necessarily bind such genomic DNA, which is in regions with chromatin structure. Therefore, it would have been obvious over the patent and its claims to make embodiments embraced by the instant specification. The Artisan would have done so in order to assess phenotype changes in the cells. Moreover, the Artisan would have a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 7,235,354

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is not persuasive. In the instant case, only a species requirement was imposed, and no restriction was made. Moreover, the various species were rejoined during prosecution. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 7,220,719, for reasons of record, as modified below due to the amendments. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method of modulating endogenous cellular gene expression, in a cell, but does do so in all of the same species of the instant claims. The specification is drawn, at its core to the ZFPs, which

includes synthetic ZFPs. Hence, in the process of performing the method, the ZFPs would necessarily bind such genomic DNA, which is in regions with chromatin structure. Therefore, it would have been obvious to make the cells. The Artisan would have done so in order to modulate gene expression of a endogenous cellular gene. Moreover, the Artisan would have had a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 7,220,719

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in the instant case, only a species requirement was imposed, and no restriction was made. Moreover, the various species were rejoined during prosecution. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 22, and 25-27 of U.S. Patent No. 7,217,509, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to methods of isolating polynucleotides through probing cellular chromatin with various chemicals and enzymes, which chemicals are taught in the specification to include fully synthetic chemicals that do not exist in

nature, and which enzymes include synthetic enzymes. Further the specification teaches the various embodiments of species. Hence, the complex in the cell is obvious, as it would form during the method of isolating the collection of polynucleotides in the claims of the patent. Therefore, the complexes and cells would be made. Moreover, there exists a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 7,217,509

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. In this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,177,766, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to computer methods of designing artificial zinc fingers. However the specification teaches such is meant to bind and activate/repress transcription of endogenous genes in cells common with each claimed genera. Hence, the whole purpose of the patent's claims is to design non-naturally occurring DNA binding sequences, to bind cellular chromatin, which may be done in vivo or in vitro. Hence, the claims are obvious as

they would be made in the use of the designed artificial zinc fingers. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 7,177,766

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,163,824, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent's claims are drawn to cells comprising synthetic zinc finger proteins. However, the specification teaches that these cells bind to DNA in the genome. Therefore, the complexes and cells would be made. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 7,163,824

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant argues that the claims are required to be obvious as drawn to cell comprising at least two zinc finger nucleases (p. 7, paragraph 2).

Such is not persuasive. The instant claims are drawn to zinc finger proteins which are non-naturally occurring, in a cell and binding to cellular chromatin. The patent's claims are drawn to cells comprising zinc finger proteins which are non-naturally occuring and bound to "target sites", which are taught in the specification to be regions comprising cellular chromatin (e.g., SUMMARY OF THE INVENTION). Moreover, the use of transformation of the cells to express the non-natural zinc fingers is taught (e.g., Id.). Hence, it would be obvious to make the cell comprising the complex comprising a non-naturally occuring zinc-finger bound to regions comprising cellular chromatin. Finally, there is no requirement for two-way analysis to arrive at the same embodiments in this case.

Applicant argues that the patent is directed to zinc-finger proteins which are known to be functional when bound to non-accessible regions (p. 7, paragraph 3, citing co-submitted Appendix A (Zhang, et al. (2000) Journal of Biological Chemistry, 275(27): 33850-60) in the response of 12/27/05 (Applicant mistakenly reciting the date of mailing, not date of record)), and argues that therefore, the patent is drawn to zinc finger proteins that bind non-accessible regions, while the present invention is drawn to zinc-fingers which bind accessible regions. (p. 7, paragraph 3.)

Such is not persuasive. The present claims do not recite a Zinc finger which binds to only to accessible regions, and the patent claims do not recite Zingers which bind only to non-accessible regions. Still further, the argument is non-persuasive to begin with. The Zinc finger has to bind, and hence, the region is by definition accessible to the Zinc finger. Zang may teach that a zinc finger protein actually bound to something to which another protein (a DNAse) could not bind, but such simply demonstrates that different proteins have different specificities.

Moreover, there is no structure in the claims or specification to determine that the Zinc fingers are different when they do or do not bind a site which is accessible or non-accessible to anther type of DNA binding protein. Hence, there is no structure to designate these claims as distinct. Lastly, there is no requirement for two way double patenting in this case.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 7,097,978for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to exposing cellular chromatin to a compound. However, the specification teaches the same cellular chromatins, and further teaches that the compound may be chimeric protein, including a ZFP. Therefore, the complexes and cells would be made. Moreover, the Artisan would have a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 7,079,978

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7,070,934, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn modulating the expression of a gene, comprising use of engineered zinc finger proteins, including non-naturally occurring molecules. However, the specification teaches the same cellular chromatins. Hence, the complexes would obviously be made in the method. Therefore, the complexes and cells would be made. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 7,070,934

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 7,067,317, for

reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to modulating angiogenesis by using zinc finger proteins to bind and increase VEGF expression, by binding specific sites. However, the specification teaches zinc finger proteins to be chimeric. Hence, the complexes would obviously be made in the method. Therefore, the complexes and cells would be made. Moreover, the Artisan would have a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 7,067,317

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. While in the patent's prosecution history, a restriction was made, no such restriction was made to restrict out the cells comprising the complex, and the only restricted compositions were to the zinc finger protein itself, and the nucleic acid encoding such. Hence, the restriction requirement does not preclude the presently claimed cells from being subject to double patenting. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,045,304, for

reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn screening for compounds and their interaction with cellular targets, comprising use of engineered zinc finger proteins. However, the specification teaches the same cellular chromatins and cell types. Hence, the complexes would obviously be made in the method. Therefore, the complexes and cells would be made with a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 7,045,304

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

While the rejection of Claim 69 is withdrawn, Claims 57, 68, 70, and 71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,026,462, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the polypeptides of the patent encode zinc finger proteins, which the specification teaches may be chimeric, and used to bind cellular DNA for increasing angiogenesis. However, the specification teaches the same

cellular chromatins and cell types. Hence, the complexes and cells would obviously be made in use of the polypeptide made by the polynucleotide. Moreover, there is a reasonable expectation of success, as the patent teaches such.

The rejection of Claim 69 is withdrawn, as the protein is taught to bind in a human cell, and to modulate angiogenesis, which is not an aspect which is affected in plants, and hence, would not appear to be a double-patenting issue.

Response to Argument – Double Patenting, 7,026,462

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant argues that the claims are required to be obvious polynucleotides encoding specific zinc finger proteins (p. 7, paragraph 2).

Such is not persuasive. The instant claims are drawn to zinc finger proteins which are non-naturally occurring, in a cell and binding to cellular chromatin. The patent's claims are drawn to polynucleotides encoding specific non-naturally occurring zinc finger proteins, and compositions for modulating angiogenesis with such polynucleotides. The specification teaches that the protein binds to regions comprising cellular chromatin in the cell, and activates transcription, thereby causing angiogenesis. Hence, the patent's claimed compositions are used to bind cellular chromatin in a cell, thereby producing a species which anticipate the present claims. Hence, the claimed cells are obvious. Lastly, the restriction requirement made in the patent's prosecution never restricted the cells comprising the complex from that of the polynucleotides, hence, no preclusion of double-patenting exists.

Applicant argues that the patent is directed to zinc-finger proteins which are known to be functional when bound to non-accessible regions (p. 7, paragraph 3, citing co-submitted

Appendix A (Zhang, et al. (2000) Journal of Biological Chemistry, 275(27): 33850-60) in the response of 12/27/05 (Applicant mistakenly reciting the date of mailing, not date of record)), and argues that therefore, the patent is drawn to zinc finger proteins that bind non-accessible regions, while the present invention is drawn to zinc-fingers which bind accessible regions. (p. 7, paragraph 3.)

Such is not persuasive. The present claims do not recite a Zinc finger which binds to only to accessible regions, and the patent claims do not recite Zingers which bind only to non-accessible regions. Still further, the argument is non-persuasive to begin with. The Zinc finger has to bind, and hence, the region is by definition accessible to the Zinc finger. Zang may teach that a zinc finger protein actually bound to something to which another protein (a DNAse) could not bind, but such simply demonstrates that different proteins have different specificities. Moreover, there is no structure in the claims or specification to determine that the Zinc fingers are different when they do or do not bind a site which is accessible or non-accessible to another type of DNA binding protein. Hence, there is no structure to designate these claims as distinct. Lastly, there is no requirement for two-way double patenting in this case.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 7,013,219, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to modulating the expression of a gene in a cells, comprising the use of what the specification describes as non-

naturally occurring zinc fingers. Hence, the complexes and cells would obviously be made in the method. Moreover, an expectation of success is present, as the patent teaches such.

Response to Argument – Double Patenting, 7,013,219

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement removing the complex comprising cell from the methods. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-61 of U.S. Patent No. 7,001,768, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to altering cellular chromatin structure in a cell, comprising administration of fusion molecules including ZFPs. Such fusion molecules are necessarily artificial and must bind the DNA to alter its structure. Hence, the complexes and cells would obviously be made in the method. Moreover there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 7,001,768

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,989,269 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to cells comprising gene-switch systems, which the specification teaches may be integrated or in plasmids, and further teaches that the ZFP may be chimeric. Hence, the complexes and cells would obviously be made in using the cells to express the genes. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,989,269

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-85 of U.S. Patent No. 6,979,539 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to inhibiting or activating the expression of a gene in a cells, comprising the use of what the specification describes as non-naturally occurring zinc fingers. Hence, the complexes and cells would obviously be made in the method. Moreover, a reasonable expectation of success is found as the patent teaches such.

Response to Argument – Double Patenting, 6,979,539

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,933,113 for

reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to modulating the expression of a gene in a cells, comprising the use of what the specification describes as non-naturally occurring zinc fingers. Hence, the complexes and cells would obviously be made in the method. Moreover, a reasonable expectation of success exists, as the patent teaches such.

Response to Argument – Double Patenting, 6,933,113

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

In light of the Arguments, the rejection of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,919,204 are withdrawn.

To wit, the restriction requirement in the prosecution history of this patent precluded the cells comprising the fusion protein and cells comprising the nucleic acid encoding it, from that of the elected group (restriction requirement of 10/3/03 and election of 10/27/03), and further, the restriction requirement was not withdrawn. Hence, double-patenting rejections are precluded.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-66 of U.S. Patent No. 6,824,978 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to modulating the expression of a cellular genes, comprising the use of what the specification and claims describe as what can only non-naturally occurring zinc fingers. Hence, the complexes and cells would obviously be made in the method. Moreover, there is an expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,824,978

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,785,613 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn processes for making

synthetic proteins, especially zinc finger proteins. However, the specification teaches using this method to make the proteins, which can then be used to bind cellular chromatin, in the various species. Hence, the complexes and cells would obviously be made in the use of the method's obtained proteins. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,785,613

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,780,590 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to identifying genes in cells, comprising the use of what the specification describes as non-naturally occurring zinc fingers. Hence, the complexes and cells would obviously be made in the method. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,780,590

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, the only restriction made was not an actual restriction, but a species requirement, at the very least, the claims are still drawn to comprising non-naturally-occuring zinc fingers. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,777,185 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to establishing associations of genes and a phenitype, comprising the use of what the specification describes as non-naturally occurring zinc fingers. Hence, the complexes and cells would obviously be made in the method. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,777,185

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,689,558 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to screening for interactions between a compound and molecular targets, comprising the use of what the specification describes as non-naturally occurring zinc fingers for binding cellular chromatin. Hence, the complexes and cells would obviously be made in the method.

Response to Argument – Double Patenting, 6,689,558

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, the restriction requirement did not preclude the cell from the claimed methods in the patent. Lastly, there is no requirement for

two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,610,489 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to predicting response to drugs, comprising the exposing cellular chromatin to drugs, which in the specification are described to include chimeric and chemical probes which are completely artificial. Hence, the complexes and cells would obviously be made in the method. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,610,489

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement made. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,607,882 for

reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to activating expression of developmentally silenced genes in cells, comprising the use of what the specification describes as non-naturally occurring zinc fingers. Hence, the complexes and cells would obviously be made in the method. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,607,882

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, the restriction requirement did not preclude the cells from being claimed with the methods claimed. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,610,489 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to predicting response to drugs, comprising the exposing cellular chromatin to drugs, which in the specification are described to include chimeric and chemical probes which are completely artificial. Hence, the

complexes and cells would obviously be made in the method. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,610,489

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement in the prosecution of the patent's application. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,599,692 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to establishing associations of genes in phenotypes, using zinc fingers which in the specification are described to include artificial zinc fingers. Hence, the complexes and cells would obviously be made in the method. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,607,882

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,534,261 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to inhibiting and activating transcription of endogenous cellular genes, comprising the exposing such genes in the cell to zinc finger proteins, which in the specification are described to include artificial zinc fingers. Hence, the complexes and cells would obviously be made in the method. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,534,261

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, the restriction requirement did not preclude the claiming of the cells. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,511,808 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to designing artificial regulatory molecules of genes, which the specification include artificial zinc fingers, and other proteins, which bind to the DNA and cause transcription. Hence, the complexes and cells would obviously be made in the use of the obtained proteins. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,511,808

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,503,717 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent are drawn to identifying genes associated with a phenotype, using exposure of cells to artificial zinc finger proteins. Hence, the complexes and cells would obviously be made in the method. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,503,717

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, there was no restriction requirement. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,453,242 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods/programs/systems of the patent are drawn selecting a target site within a target sequence for binding a zinc finger, which in the specification are

described to include artificial zinc fingers, which are used to bind cellular chromatin subsequent to making. Hence, the complexes and cells would obviously be made subsequent to the methods/programs/systems of the patent. Moreover, there is a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,453,242

Applicant's argument of 2/26/08 have been fully considered but are not found persuasive.

Applicant again argues that the claims are drawn to methods, and in the instant case, a restriction was imposed which precludes double-patenting of the claims due to the present claiming of compositions (pp. 6-7, paragraph bridging).

Such is again not persuasive. Again, in this case, the restriction requirement did not preclude claiming the cell comprising complexes presently claimed. Lastly, there is no requirement for two-way obviousness analysis in these claims, and hence, exact common embodiments are not even required.

Claim Rejections - 35 USC § 112 – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of the amendments, the rejections of Claims 57 and 68-71 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **for comprising new matter**, are withdrawn.

To wit, from the confluence of the specification, it is clear that Applicant possessed non-naturally occurring zinc-fingers.

Claim Rejections - 35 USC § 102 – MacKay

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejections of Claims 57, 68, and 70 under 35 U.S.C. 102(b) as being anticipated by MacKay, et al. (1998) Journal of Biological Chemistry, 273(46): 30560-67, are withdrawn.

To wit, Applicant has amended the claims to comprise the complex of the zinc-finger protein, bound to cellular chromatin, (by amendment to include the previous limitations of cancelled claim 66). Paragraphs 0042-0044 of the Application's publication 2002/0064802 make clear that the cellular chromatin does not read on episomal DNA within the cell.

Claim Rejections - 35 USC § 102 - Schwechheimer

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In light of the amendments, the rejections of Claims 57, and 69 under 35 U.S.C. 102(b) as being anticipated by Schwechheimer, et al. (1998) Plant Molecular Biology, 36: 195-204, are withdrawn.

To wit, the claims now encompass the zinc finger protein bound to cellular chromatin, within a cell, and hence, the claims are no longer anticipated as Schwechheimer taught episomal DNA bound to the zinc finger.

Claim Rejections - 35 USC § 102 - Knoke

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In light of the amendments, the rejections of Claims 57, 68, and 71 under 35 U.S.C. 102(b) as being anticipated by Knoke, et al. (1999) Human Genetics, 104: 257-61, are withdrawn.

To wit, the proteins bind to plasmids, not cellular chromatin.

Claim Rejections - 35 USC § 102 - Olivera

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In light of the amendments, the rejections of Claims 57 and 70, under 35 U.S.C. 102(b) as being anticipated by Oliveira, et al. (1998) Chromosome Research, 6: 205-11 are withdrawn.

To wit, Olivera's non-naturally occurring molecules are not zinc finger proteins.

Olivera teaches fluorescence in situ hybridization of heterochromatin in fish cells (e.g., ABSTRACT; FIGURE 2). Such molecules used in FISH techniques are non-naturally occurring. Still further, the DNA that is bound appears to contain heterochromatin sites and euchromatin sites (e.g., p. 210), hence, the DNA can be assayed for chromatin structure with probes therefore.

Therefore, the claims are anticipated.

Claim Rejections - 35 USC § 102 - Boyes

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In light of the amendments, the rejection of Claim 57 under 35 U.S.C. 102(b) as being anticipated by Boyes, et al. (1998) Journal of Molecular Biology, 279: 529-44, is withdrawn.

To wit, Boyes's experiments are performed with cellular chromatin *in vitro*, outside of the cell (e.g., p. 530).

Claim Rejections - 35 USC § 102 – co-invented patents

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 57 and 68-71 remain rejected under 35 U.S.C. 102(e) as being anticipated by each of US Patent Nos.: 7,235,354; 7,220,719; 7,177,766; 7,163,824; 7,045,304; 7,013,219; 6,989,269; 6,979,539; 6,933,113; 6,824,978; 6,785,613; 6,780,590; 6,777,185; 6,689,558; 6,607,882; 6,599,692; 6,534,261; and 6,453,242, for reasons of record.

The applied references have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As shown in the double patent rejections above, each of these patents claim embodiments which make obvious the various claimed subject matter. Moreover, the specifications each teach essentially the same subject matter with regard to the artificial proteins and artificial chemicals which bind to the cellular chromatin in the cell and/or or outside the cell. Hence, the claims are anticipated.

Response to Argument - 102(e) rejections with co-inventors listed

Applicant's argument of 2/26/08 has been fully considered but is not found persuasive.

Applicant argues that anticipation is a rigorous standard and the limitations must appear identically in each reference for the 102 to stand, that inherency cannot established by

possiblities, and hence, the Examiner must show that the Zinc finger is necessarily and inevitably bound to the accessible regions of chromatin (pp. 13-14).

Such is not persuasive. For each case, the methods or compositions are taught in the specification to bind to cellular chromatin. For example, Patent No. 7,235,354 teaches that the recombinant zinc finger proteins are used for functional genomics and target validation (e.g., ABSTRACT), and that the zinc fingers are chimeric (e.g., paragraph 9 of the Summary of Invention), and that they bind to cellular chromatin (e.g., paragraph 2 of "Regulatory Domains"), and further they are clearly bound in the cell (e.g., Claims). Hence, embodiments encompassed by the claims are anticipated, and also lead to an obviousness-type double patenting rejection, because the claims are not coextensive with those presently claimed.

Applicant argues that the rejections against 6,534,261 was previously withdrawn by the previous examiner, and that it was because the Examiner could not demonstrate that the zinc finger proteins are necessarily binding to an accessible region of chromatin (p. 14, paragraph 4).

Such is not persuasive. The claims are distinct from what was claimed at that time, and further, the region has to be accessible to the zinc finger protein, and hence, it does bind to an accessible region of chromatin. In the 6,534,261 patent, the claims are even drawn to inhibiting transcription. It would be ridiculous to argue that the protein does not bind its binding site, otherwise it would not inhibit transcription. Further, again, the site is accessible, otherwise the zinc finger protein would not bind.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57, 68, 70, and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Shin, et al. (1999) Proceedings of the National Academy of Sciences, USA., 96: 2880-84.

Shin teaches several zinc-finger constructs containing amino-terminal enterokinase tags (e.g., FIGURE 1), which are utilized by expressing them in human cells (e.g., HeLa and 293 cells, p. 2881, col. 1, paragraph 3). Moreover, the PHS and PAP-A mutants localize to the nucleus, and inhibited PTCH1 transcription from the normal cellular gene, which is located in a region comprising cellular chromatin, and is accessible, otherwise it would not inhibit transcription (e.g., ABSTRACT). Hence, the complex, absent reason to believe otherwise, the complex was formed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57, 68, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Stacey, et al. (1999) The Plant Cell, 11: 349-63.

Stacey teaches mutants of the zinc-finger containing protein COP1, from arabadopsis, which are fused to e.g., GFP (e.g., ABSTRACT). Such proteins are expressed in plant cells, and can localize to the nucleus upon exposure to light (e.g., Figure 2 and pages 350-51), and further, those that do localize to the nucleus are further shown to grow with photomorphogenic effects (e.g., p. 355). Hence, absent reason to believe otherwise, this zinc-finger containing mutant bound to a complex in those cells and activated genes to produce the photomorphogenic effects. Moreover, the site is accessible, otherwise the zinc finger protein could not bind it. Therefore, the complex in the plant cell is found.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Acting Examiner of Art Unit 1633